IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF LOUISIANA

RONALD HOYT and **SANDRA HOYT,** *Plaintiffs*, v. **EXACTECH, INC.** and **EXACTECH, US, INC.**, *Defendants.*	:	Civil Action No.: 3:22-cv-00568 **COMPLAINT & DEMAND FOR JURY TRIAL**

NOW COMES Plaintiffs RONALD HOYT ("Plaintiff") and SANDRA HOYT (hereafter collectively as "Plaintiffs"), by and through the undersigned attorneys, and bring this action against EXACTECH, INC. ("EXACTECH") and EXACTECH US, INC. ("EXACTECH US") (hereafter collectively as "Defendants"), for personal injuries suffered as a proximate result of the implantation of an OPTETRAK total left knee arthroplasty revision with polymer wear and laxity, and three total knee replacements, and allege as follows:

NATURE OF THE ACTION

1. This is an action for damages relating to Defendants' development, designing, testing, assembling, manufacturing, packaging, monitoring, labeling, preparing, distribution, marketing, supplying, storage, and/or selling of the Optetrak patella and Comprehensive Total Knee System (hereafter as "Optetrak Device"). The Optetrak Device as referred to in this Complaint includes the Optetrak Comprehensive Total Knee System and/or the Optetrak Logic Comprehensive Knee System. Sturdiness

2. Thousands of patients, like Plaintiff RONALD HOYT, have been, and/or will be,

required to undergo extensive revision surgery to remove and replace defective Optetrak Devices due to a recent recall of these devices which first revealed to patients and surgeons that the polyethylene components within the prosthesis prematurely degrades over time causing an inflammatory response resulting in bone necrosis (death) also known as osteolysis. The recall notice admits that the recall and problems arose from failure to properly package the polyethylene insert component of the Optetrak Device.

3. As a result of the Exactech Defendants' failure to properly package the Optetrak Device prior to distribution, the polyethylene liner prematurely degraded and Plaintiff required revision surgeries due to severe pain, swelling, and instability in the knee and leg. These injuries were caused by early and preventable wear of the polyethylene insert and resulting component loosening and/or other failures causing serious complications including tissue damage, osteolysis, permanent bone loss and other injuries.

4. Recipients of the Optetrak Device, like the Plaintiff, have been required to undergo revision surgeries well before the estimated life expectancy of a knee implant and at a much higher rate than should reasonably be expected for devices of this kind and have suffered pain and disability leading up to and after the revision surgery.

5. Despite knowledge that the Optetrak Device was defective and resulted in premature failures and accompanying complications, Defendants only first issued a nationwide recall on February 7, 2022, advising the public that "most of our inserts since 2004 were packaged in out-of-specification… vacuum bags that are oxygen resistant but do not contain a secondary barrier layer containing ethylene vinyl alcohol (EVOH) that further augments oxygen resistance."

6. As a direct and proximate result of the defective nature of Defendants' Optetrak Device surgically implanted in Plaintiff which necessitated premature removal, Plaintiff suffered

and will continue to suffer serious personal injuries, including pain, impaired mobility, rehabilitation, medical care, loss of enjoyment of life, and other medical and non-medical sequalae.

7. Plaintiffs brings this action for personal injuries suffered as a proximate result of failure of the Optetrak Device.

8. Plaintiffs accordingly seeks compensatory and punitive damages, and all other available remedies provided to Plaintiffs under the law because of injuries RONALD HOYT and SANDRA HOYT sustained due to the Defendants' negligent, reckless and wrongful conduct.

JURISDICTION & VENUE

9. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy exceeds Seventy-Five Thousand Dollars ($75,000.00), exclusive of interest and costs, and because there is complete diversity of citizenship between the Plaintiffs and all Defendants.

10. The court has personal jurisdiction over Defendants because at all relevant times they have engaged in substantial business activities in the State of Louisiana. At all relevant times Defendants transacted, solicited, and conducted business in Louisiana through their employees, agents, and/or sales representatives, and derived substantial revenue from such business in Louisiana.

11. Venue is proper in this judicial district and division pursuant to 28 U.S.C. § 1391 because Plaintiffs are residents and citizens of Greenwell Springs, Louisiana.

THE PARTIES

12. Plaintiff RONALD HOYT is a resident and citizen of Greenwell Springs, East Baton Rouge Parish, Louisiana.

13. Plaintiff SANDRA HOYT is a resident and citizen of Greenwell Springs, East

Baton Rouge Parish, Louisiana.

14. At all times relevant to this action, Plaintiff SANDRA HOYT was and is the lawful and loving spouse to Plaintiff RONALD HOYT.

15. Defendant EXACTECH, INC. is a Florida corporation with its principal place of business located at 2320 NW 66th Court, Gainesville, Florida 32653.

16. Defendant EXACTECH, INC. develops, manufactures, packages, stores, distributes, markets and sells orthopedic implant devices, including Optetrak Devices and related surgical instrumentation throughout the United States, including in and throughout the United States and the state of Louisiana.

17. Defendant EXACTECH, INC. manufactured the Optetrak Device implanted in Plaintiff RONALD HOYT.

18. At all times relevant to this action, Defendant EXACTECH, INC. tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Optetrak Device in interstate commerce and generated substantial revenue as a result.

19. Defendant EXACTECH US, INC., a wholly owned subsidiary of Defendant EXACTECH, INC., is a Florida corporation with its principal place of business located at 2320 NW 66th Court, Gainesville, Florida 32653.

20. According to public filings, Defendant EXACTECH US, INC., conducts Defendants' U.S. sales and distribution activities.

21. EXACTECH US, INC. is engaged in the business of designing, developing, testing, assembling, selecting, manufacturing, packaging, labeling, preparing, distributing, marketing, supplying, warranting, selling, and introducing Defendants' products, including Optetrak Devices,

into commerce throughout the United States.

22. Upon information and belief, the Optetrak Devices manufactured by Defendant EXACTECH, INC. were distributed by Defendant EXACTECH US, INC. throughout the United States, including in Zachary, Louisiana where Plaintiff received his implants.

23. At all times relevant to this action, Defendant EXACTECH US, INC., tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, stored, promoted, advertised, marketed, distributed, and/or sold the Optetrak Device in interstate commerce and generated substantial revenue as a result.

FACTUAL BACKGROUND

24. Upon information and belief, the first Optetrak total knee system was available for implantation in 1994, building upon technology licensed from the Hospital for Special Surgery.

25. At all times material hereto, the Exactech Defendants designed, developed tested, assembled, selected, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, warranted, and/or sold the Optetrak Comprehensive Total Knee System and the Optetrak Logic Comprehensive Knee System to hospitals in many states.

26. Exactech Defendants obtained 510(k) clearance from the Food and Drug Administration ("FDA") for various Optetrak total knee system devices and components between 1994 and 20 17 including under the names: Optetrak, Optetrak Logic and Truliant.

27. 510(k) clearance is distinct from the FDA's pre-market approval ("PMA") process in that clearance does not require clinical confirmation of safety and effectiveness and as such the manufacturer retains all liability for the assertions of safety and effectiveness.

28. 510(k) clearance only requires the manufacturer to notify the FDA under section 510(k) of the Medical Device Amendments of 1976 to the Food Device Cosmetic Act (MDA) of

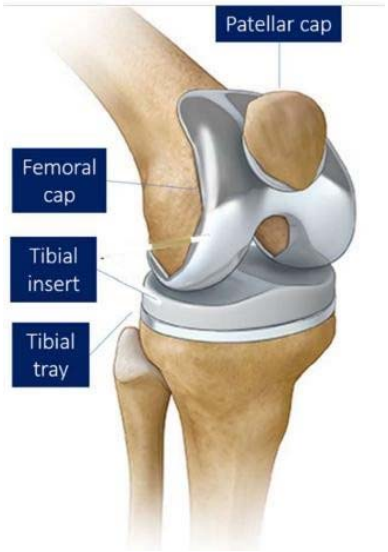
its intent to market a device at least 90 days prior to the device's introduction on the market, and to explain the device's substantial equivalence to a pre-MDA predicate device. The FDA may then "clear" the new device for sale in the United States.

29. All the component parts comprising Plaintiff's Optetrak Device were cleared for marketing by the FDA pursuant to 510(k) process or were marketed without receiving either 510(k) clearance or PMA approval by the FDA.

30. The Optetrak Total Knee System is classified as a knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis. It features a mix of polyethylene and metal-based components.

31. According to the Exactech Defendants, the device "introduces novel implants and instruments to make the total knee procedure, easier, faster and more consistent, improving patient satisfaction for a more diverse population requiring total knee replacements."

32. The Optetrak Device is comprised of the following parts: a patellar cap, femoral cap, tibial insert, and tibial tray, as shown above. The patellar cap and tibial insert are made of polyethylene.



33. The patellar cap and tibial insert are made of polyethylene.

34. The Exactech Defendants touted the Optetrak Device as being first-in-class in their product brochures.

35. In their marketing materials, the Exactech Defendants promised that the Optetrak Device had excellent long-term clinical outcomes and that "surgeons and patients can have every confidence in the performance and longevity of the Optetrak knee system."

36. Exactech Defendants promoted their Optetrak Devices as a system with nearly three decades of clinical success and proven outcomes for patients around the world because of an improved articular design resulting in low polyethylene stresses.

37. However, Optetrak Devices have performed poorly when compared to its competitors. For example, the Australian Orthopaedic Association, a preeminent, internationally recognized orthopedic implant registry, has identified the Optetrak as an implant with a higher-than-expected rate of revision.

38. According to the 2020 Australian National Joint Replacement Registry, the rate of revision for a total knee replacement utilizing an Optetrak tibial component with a Optetrak-CR femoral component was 8.5% at ten years and 10.2% at ten years when implanted with a Opetrak-PS femoral component which far exceeds international guidelines for accepted revision rates.

39. Per the recommendations established by the International Benchmarking Working Group and applied by the Australian Orthopaedic Association, the Optetrak Devices do not qualify for a "superiority benchmark" or even a "non-inferiority benchmark."

40. At all times relevant, Defendants have been aware of a high rate of early failures associated with the Optetrak Device.

41. Upon information and belief, by 2012, the Exactech Defendants had further clinical

evidence that Optetrak Devices were failing at a rate higher than promoted. Reports in the Manufacturer and User Facility Device Experience (MAUDE) indicate instances of revision due to "loose tibial component", "aseptic loosening", "pain and visible loosening", "polyethylene deformation", "polyethylene worn", and "pain, limited mobility, knee swelling and sensitivity" due to "loose" joint.

42. Upon information and belief, in 2013, complaints continued to be reported. Some examples include revision for "tibial loosening" just two years postoperatively, "revision due to tibial loosening", "during revision, the tibial component was found to be loose and easily removed", "revision of knee component due to loosening", "revision due to pain and loosening."

43. Upon information and belief, the complaints of early onset failures continued in 2014. Some examples include "revision due to tibial loosening", "tibial loosening", "revision of optetrak knee components due to tibial loosening", "revision due to pain and loosening", "revision of optetrak knee components due to aseptic loosening", several reports described as "revision of knee components due to tibial loosening", and "revision of optetrak knee components reportedly due [to] aseptic loosening".

44. The general practice in orthopedic implant surgeries generally, and with Exactech implants specifically, is for the sale representative of the manufacturer, in this case Exactech's authorized representative and agent, hereinafter "the sales rep", to be present at the time of surgery to provide implant components to the surgeon, relieving the hospital of the responsibility for having on stock all potential sizes and components that may be needed in surgeries. This practice includes the original implant surgery and any revision surgery.

45. The sales representatives of Exactech observed many instances of premature failures of the Optetrak Device with plain evidence upon revision of polyethylene debris that needed to get

removed, a/k/a "debrided", visible bone loss or osteolysis and plainly loose components that were easy to remove due to lack of fixation. Often these sales reps would take the component from the surgeon to return to the company for inspection and analysis.

46. The sales representatives of Exactech were under a duty to report these findings to the engineering and medical departments of Exactech who were under a duty to then do an investigation, analyze the removed component when available, also known as "retrieval analysis," and honestly and thoroughly report such findings to the FDA and the surgeons.

47. Despite Defendants' knowledge of early onset failures of the Optetrak Device, Defendants continued to manufacture, promote, and distribute the Optetrak Device without alerting surgeons, patients, or the FDA of the potential increased risks of early onset failures of the Optetrak Device.

48. Defendants never changed the labeling, marketing materials or product inserts to adequately and accurately warn patients or physicians of the associated increased risks of early failure due to loosening and/or polyethylene wear.

49. Not until August 30, 2021 did the Defendants take some action and issued a partial recall of all Optetrak All-polyethylene tibial components, including the OPTETRAK All-polyethylene CC Tibial Components; OPTETRAK All-polyethylene CR Tibial Components; OPTETRAK All-polyethylene CR Tibial Sloped Components; OPTETRAK All-polyethylene PS Tibial Components; OPTETRAK HI-FLEX PS Polyethylene Tibial Components; OPTETRAK Logic All-polyethylene CR Tibial Components; OPTETRAK Logic All-polyethylene CRC Tibial Components; OPTETRAK Logic All-polyethylene PSC Tibial Components; OPTETRAK Logic Modular PS Tibial Components; OPTETRAK Logic RBK PS Tibial Components; TRULIANT CR Tibial Inserts; TRULIANT CRC Tibial Inserts; TRULIANT PS Tibial Inserts; and

TRULIANT PSC Tibial Inserts.

50. In issuing the August 2021 recall, Defendants stated "inserts were packaged in vacuum bags that lacked an additional oxygen barrier layer." *See* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?ID=189266

51. According to the FDA website, "Exactech began notification to distributors and sales representatives on about 08/30/2021 via letter titled "URGENT MEDICAL DEVICE RECALL." Actions being taken by Exactech included removing all Knee and Ankle UHMWPE products labeled with an 8-year shelf life and not packaged in EVOH/Nylon bags. This will be performed in a phased approach over the next 12 months. Phase 1 includes immediately return all knee and ankle UHMWPE devices labeled with an 8-year shelf life that will be 5 years old or older by 08/31/2022 not packaged in EVOH/Nylon bags. Phase 2 includes, between 05/31/2022 to 08/31/2022, returning all remaining knee and ankle UHMWPE devices labeled with an 8-year shelf life not packaged in EVOH/Nylon bags." *Id.*

52. Despite initial communications with distributors and sales representatives, Defendants did not issue any communications to surgeons who had implanted Optetrak Device with a recalled polyethylene component or to patients who had received an Optetrak Device with a recalled polyethylene component until months later in February 2022.

53. On February 7, 2022, Defendants issued an "Urgent Medical Device Correction" in which it informed health care professionals that:

> After extensive testing, we have confirmed that most of our inserts manufactured since 2004 were packaged in out-of-specification (referred to hereafter as "non-conforming") vacuum bags that are oxygen resistant but do not contain a secondary barrier layer containing ethylene vinyl alcohol (EVOH) that further augments oxygen resistance. **The use of these non-conforming bags may enable increased oxygen diffusion to the UHMWPE (ultra-high molecular weight polyethylene) insert, resulting in increased oxidation of the material relative to inserts**

> **packaged with the specified additional oxygen barrier layer. Over time, oxidation can severely degrade the mechanical properties of conventional UHMWPE, which, in conjunction with other surgical factors, can lead to both accelerated wear debris production and bone loss, and/or component fatigue cracking/fracture, all leading to corrective revision surgery.**
>
> *See* https://www.exac.com/wp-content/uploads/2022/02/Exactech-DHCP letter.02.07.2022.pdf

54. The "Urgent Medical Device Correction" went on to further state that Defendants were expanding the recall to include all knee arthroplasty polyethylene inserts packed in non-conforming bags regardless of label or shelf life. The components subject to the recall now included: OPTETRAK®: All-polyethylene CR Tibial Components, All-polyethylene PS Tibial Components, CR Tibial Inserts, CR Slope Tibial Inserts, PS Tibial Inserts, HI-FLEX® PS Tibial Inserts; OPTETRACK Logic®: CR Tibial Inserts, CR Slope Tibial Inserts, CRC Tibial Inserts, PS Tibial Inserts, PSC Tibial Inserts, CC Tibial Inserts; and TRULIANT®: CR Tibial Inserts, CR Slope Tibial Inserts, CRC Tibial Inserts, PS Tibial Inserts, PSC Tibial Inserts. *Id.*

55. It is estimated that a total of 147,732 inserts implanted in the United States since 2004 were produced with non-conforming packaging. *Id.*

56. Defendants further acknowledged the original Optetrak knee system has shown statistically significant higher overall revision rates compared to other total knee arthroplasties in the Australian, United Kingdom and New Zealand joint registries. *Id.*

57. Specifically, reasons for revision associated with polyethylene wear, including loosening, lysis, and pain, were increased three-to seven-fold with the Opetetrak total knee replacement combination of the Optetrak-PS/Optetrak according to the 2021 Australian National Joint Replacement Registry with revision diagnoses related to accelerated polyethylene wear possibly related to the non-conforming packaging. *Id.*

58. Implanting surgeons were advised in the February 2022 notice to contact patients

previously implanted with recalled components and to schedule an evaluation if the patient is experiencing any new or worsening knee swelling, pain while walking, inability to bear weight, grinding or other noise, instability, or any new symptoms of clicking in the knee. *Id.*

59. Furthermore, Defendants advised surgeons that revision surgery should be considered for patients who exhibit premature polyethylene wear. *Id.*

60. Based on Defendants' own representations, since 2004, Defendants manufactured, promoted, and distributed the Optetrak Device without ensuring the polyethylene components were properly packaged to prevent or minimize oxidation. At no point until August 2021 did Defendants first modify the packaging to address this defect.

61. In approximately 2017 – 2018, Exactech, Inc. was in the process of being acquired by the Private Equity Group TPG Capital which in February 2018 successfully completed a merger agreement. As a result, TPG acquired all the issued and outstanding common stock of Exactech. In connection with the transaction, Exactech's founders, CEO and certain other management shareholders exchanged a portion of their shares in the transaction, for new equity securities in the post-closing ownership of the Company. *See* https://www.exac.com/exactech-announces-completion-of-merger-with-tpg-capital/

62. Disclosure of knowledge of the improper packaging and excessive premature failure rates could have harmed this transaction.

63. At all times relevant to this action, Defendants were aware of the Optetrak Device's propensity to undergo substantial early polyethylene wear consisting of the degradation and breakdown of the plastic chemicals causing toxicity to the tissue and bone and component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery and its attendant complications in patients.

64. At all times relevant to this action, Defendants failed to acknowledge the manufacturing defects in the Optetrak Device due to poor and inadequate quality assurance procedures and due to a wanton and reckless disregard for public safety. Defendants also failed to implement or utilize adequate safeguards, tests, inspections, validation, monitoring, and quality assessments to ensure the safety of the Optetrak Device.

65. At the time the Optetrak Device was manufactured and sold to patients, including Plaintiff, the device was defectively manufactured, packaged and unreasonably dangerous, and did not conform to the federal regulations subjecting patients to unreasonable risks of injury.

66. At all times relevant to this action, the Exactech Defendants' inadequate manufacturing processes also led to material flaws in the quality systems at its manufacturing, packaging, storage and distribution facilities.

67. During manufacturing and distributing the Optetrak Device, the Exactech Defendants failed in several ways, including, without limitation, by:

a. failing to conduct adequate mechanical testing, including oxygen-resistance or other wear testing for the components, subassemblies, and/or finished Optetrak Device;

b. failing to test an adequate number of sample devices on an ongoing basis;

c. failing to take adequate steps to specifically identify failure modes with clarity and to suggest methods to monitor, avoid, and/or prevent further failures;

d. failing to identify and/or note the significance of any testing that resulted in failure of the Optetrak Device;

e. failing to take corrective actions to eliminate or minimize further failures of

the Optetrak Device;

f. failing to adequately explain packaging specifications for the components, subassemblies, and/or finished Optetrak Device;

g. failing to perform adequate quality control before the components, subassemblies, and/or finished Optetrak Device were distributed;

h. failing to properly address reports from their sales representatives who reported their observations while attending revision surgeries where evidence of polyethylene debris and osteolysis was apparent and noted by the surgeons and the sales representatives themselves;

i. failing to timely implement corrective action and investigations to understand the root cause of these failures while continuing to sell the components knowing they would be implanted into the bodies of thousands of people; and

j. Becoming aware of the potential cause or causes but unreasonably avoiding informing patients and surgeons and delaying the ability to minimize damages as the devices continued to degrade and do damage in the patients' bodies.

68. On or before the date of Plaintiff's initial knee replacement surgery, the Exactech Defendants knew or should have known the Optetrak Device was failing and causing serious complications after implantation in patients. Such complications included, but were not limited to, catastrophic polyethylene wear including the deposition of plastic particulate wear debris throughout the knee, a high rate of component loosening, and overall early system failure resulting in tissue destruction, osteolysis, and other injuries causing severe pain, swelling, instability and

dysfunction in the knee and leg necessitating revision surgery.

69. The Exactech Defendants as manufacturers of orthopedic devices know that each surgery, especially a revision surgery, is always more complicated than an initial knee replacement surgery and is fraught with serious risks of infection, anesthesia errors, dislocations and other serious complications that should be avoided.

70. The Exactech Defendants, however, ignored reports of early failures of their Optetrak Device and failed to promptly investigate the cause of such failures or issue any communications or warnings to orthopedic surgeons and other healthcare providers.

71. Before the date of Plaintiff's initial knee replacement surgery, the Exactech Defendants knew or should have known that the Optetrak Device was defective and unreasonably dangerous to patients, that the product had an unacceptable failure and complication rate, and that the product had a greater propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients.

RONALD HOYT – IMPLANT AND REVISION SURGERY

72. In approximately 2010, Plaintiff RONALD HOYT underwent a left total knee arthroplasty, that was an Optetrak Device, at Lane Regional Medical Center, located in Zachary, Louisiana.

73. In approximately 2016, Plaintiff underwent a left total knee arthroplasty revision due to polymer wear and laxity, with an Exactech Optetrak Device, at Lane Regional Medical Center, located in Zachary, Louisiana.

74. In the years following the December 2016 left total knee arthroplasty, Plaintiff began having persistent pain that required multiple aspirations and lab work which were negative

for infection.

75. On or approximately in 2021, Plaintiff RONALD HOYT underwent a total left knee replacement revision surgery with removal of all Exactech knee components and was implanted with non-Exactech components. Catastrophic polyethylene wear as well as osteolysis, and the surgeon concluded that "is obviously the cause of the problem." The post-operative diagnosis noted that the Exactech Optetrak Device component failed due to polyethylene failure.

76. Plaintiff continues to experience daily pain and discomfort in his knee which limits his activities of daily living and impacts his quality of life.

77. Further, Defendants, through its affirmative misrepresentations and omissions, actively concealed from Plaintiffs and Plaintiffs' health care providers the true and significant risks associated with the Optetrak Device and the need to vigilantly do diagnostic procedures to promptly diagnose the insidious process of the toxic polyethylene particles degrading and causing osteolysis.

78. Defendants know that after the one-year checkup following a total knee arthroplasty, typically patients are not expected to return for monitoring absent problems. Thus, Defendants knew that unless they informed surgeons to call their patients back for periodic radiologic monitoring that polyethylene chemical degradation and attendant osteolysis could be occurring unchecked until it reached the stage of severe bone loss.

79. As a direct, proximate, and legal consequence of the defective nature of the Optetrak Device as described herein, Plaintiff has suffered and continues to suffer permanent and debilitating injures and damages, including but not limited to, significant pain and discomfort; gait impairment; poor balance; difficulty walking; component part loosening; soft tissue damage; bone loss; and other injuries presently undiagnosed, which all require ongoing medical care.

80. As a further direct, proximate, and legal consequence of the defective nature of the Optetrak Device, Plaintiffs have sustained and will sustain future damages, including but not limited to cost of medical care; rehabilitation; home health care; loss of earning capacity; mental and emotional distress and pain and suffering.

TOLLING OF STATUTE OF LIMITATIONS

81. Plaintiff sustained injuries caused by the latent effects of exposure to polyethylene and the resins used to process the polyethylene and the degradation byproducts of those toxic materials.

82. The breakdown and wear of polyethylene, a plastic, leads to the release of toxic compounds, including chemical additives and nanoplastics. *See* Rillig, Matthias C. *et al.*, "The Global Plastic Toxicity Debt," *Environ. Sci. Technol.* 2021, 55, 2717-2719.

83. All plastics contain additional chemicals or additives and may contain impurities such as catalyst residues, unreacted monomers or breakdown products which possess toxic properties that can adversely affect human health. *Id.*

84. A comparison of muscle tissue from patients implanted with ceramic liners versus polyethylene liners during total hip arthroplasty demonstrated decreased osteolysis and capsule atrophy as well as less structural change to the muscles. *See* Hernigou, Phillippe *et al.*, "Ceramic-on-ceramic THA Associated with Fewer Dislocations and Less Muscle Degeneration by Preserving Muscle Progenitors," *Clin Orthop Relat Res* (2015) 473:3762-3769.

85. In patients who develop osteolysis, there is osteolysis-associated reduced bone regenerative capacity with a decreased in mesenchymal stem cells (MSCs) that is accompanied by reduced muscle mass and increased fatty degeneration. *Id.*

86. For polyethylene implants with resulting osteolysis, a "possible mechanism was

evaluated by an experimental study demonstrating that contact PE (polyethylene) particles inhibit the osteogenic activity of osteoprogenitor cells… which may result in reduced periprosthetic bone regeneration." *Id.*

87. To date, most plastic chemicals remain unknown and the toxic hazards of potentially thousands of chemicals humans are exposed to remain unknown, and thus, unregulated. *See* Zimmerman, Lisa *et al.*, "Plastic Products Leach Chemicals That Induce *In Vitro* Toxicity under Realistic Use Conditions," *Environ. Sci. Technol.* 2021, 55, 11814-11823.

88. Plastics contain several thousand extractable chemicals which induce *in vitro* toxicity. *Id.*

89. "Our study highlights that plastic products leach chemicals triggering toxicity… the prevalent antiandrogenicity is an indicator for the leaching of endocrine-disrupting chemicals relevant for human health. Our results also show that many more chemicals are migrating from plastics than previously known." *Id.*

90. Furthermore, gamma-sterilized ultra-high molecular weight polyethylene contains macroradicals that will react with available oxygen in air or dissolved in bodily fluids. Kurtz, Steven M., *UHMWPE Biomaterials Handbook*, "Packaging and Sterilization of UHMWPE" (2016).

91. By virtue of Defendants' recall notice and representations on their website, Defendants describe a process by which sterilization of the tibial insert is achieved by gamma radiation in a reduced oxygen environment by use of oxygen barrier packaging. *See* https://www.exac.com/wp-content/uploads/2022/02/Exactech-DHCP letter.02.07.2022.pdf; "Optimizing Polyethylene Materials to the Application: When it Comes to Manufacturing Methods, Hips are Not Knees," *available at* https://www.exac.com/optimizing-polyethylene-

materials-to-the-application/ (March 14, 2017).

92. "Gamma sterilization… initiate[s] a complex cascade of chemical reactions in the polymer, which ultimately result[s] in oxidation and subsequent degradation of material properties." *See UHMWPE Biomaterials Handbook.*

93. Development of osteolysis and bone loss are latent conditions caused by years of exposure to the unknown, toxic properties of polyethylene that could not be appreciated until the Exactech recalled their devices for the first time in February of 2022.

94. Plaintiff exhibited due diligence but did not possess technical, scientific, or medical knowledge and information sufficient to ascertain the cause of his injuries until after Defendants initiated a recall process of the Optetrak Device in February of 2022.

95. Defendants, through its affirmative misrepresentations and omissions, actively concealed from Plaintiff and Plaintiff's healthcare providers the true and significant risks associated with the Optetrak Device.

96. Following implantation of the Optetrak Device, Plaintiff and Plaintiff's healthcare providers relied on Defendants' continued representations that the Optetrak Device had excellent long-term clinical outcomes.

97. Defendants made these representations with knowledge of their falsity given their knowledge of reports of high failure rates.

98. As early as 2007, the Australian Joint Registry identified the Optetrak Device as having a higher than anticipated rate of revision.

99. According to the Australian Joint Registry published in 2007, use of the Optetrak-PS femoral component with an Optetrak tibial component resulted in a 6.23% revision rate at three years and 6.64% revision rate at four years. The Registry identified use of these components as

"Individual Primary Total Knee Prostheses with higher than anticipated revision rates either alone or in combination."

100. The cumulative rate of revision with use of the Optetrak-PS femoral component and an Optetrak tibial component continued to increase. Data from the 2008 and 2009 Australian Joint Registry demonstrated a revision rate of 6.7% and 7.0% at five years, respectively.

101. By 2010, the use of the Optetrak-PS femoral component and Optetrak-PS tibial components were "identified and no longer used" as a result of a 21% cumulative revision rate at five years. This rate increased to 22.7% the following year.

102. Identification of problems with the Optetrak-PS tibial component continued to grow. According to the 2015 registry data, "[t]he Optetrak PS all-polyethylene prosthesis has a cumulative percent revision of 19.4% at seven years."

103. Defendants themselves have acknowledged, "[e]very Exactech Optetrak TKR polyethylene component combination demonstrated statistically significant increased revision rates compared to other TKR systems," citing 2021 Australian Registry data, however, data demonstrating high rates of premature failure were available to Defendants as early as 2007. *See* https://www.exac.com/wp-content/uploads/2022/02/Exactech-DHCP letter.02.07.2022.pdf

104. The Optetrak Device had similarly high failure rates as documented in the United Kingdom National Joint Registry. In 2015, the revision rate for the Optetrak Device was 5.02% at seven years and 6.92% at ten years. In 2016, the revision rate for the Optetrak Device was 5.15% at seven years and 7.79% at ten years. In 2017, the revision rate for the Optetrak Device was 5.23% at seven years and 7.45% at ten years. In 2018, the revision rate for the Optetrak CR was 5.53% at seven years and 7.61% at 10 years.

105. The failure rates for the Optetrak Device in the UK Registry were consistently

higher compared to other knee replacement devices.

106. Defendants sold these implants worldwide and had a duty to monitor the international registries to assess how their prostheses were faring. Unfortunately, since the United States does not have a single payor health system, there is no national registry and doctors in the Unites States are not privy to nor expected to be aware of such data from other continents.

107. Defendants never informed physicians of the high failure rates associated with the Optetrak Devices reported annually in the international registries.

108. Although clinical evidence demonstrated that Optetrak Devices were failing at a rate higher than promoted with instances of excessive revision rates due to device loosening and polyethylene wear, Defendants failed to initiate a recall earlier or issue any communications to healthcare providers that patients should be monitored.

109. Furthermore, earlier disclosure of these failure rates could have impacted the sale of the company to private equity.

110. As a result of Defendants' actions, Plaintiff and Plaintiff's healthcare providers were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified herein, and that those risks were the result of defects in the product due to Defendants' acts, omissions, and misrepresentations.

111. Accordingly, no limitations period ought to accrue until such time as Plaintiff knew or reasonably should have known of some causal connection between Plaintiff being implanted with the Optetrak Device and the resulting harm later suffered by Plaintiff as a result by reason of Defendants' fraudulent concealment that resulted in the recall of their devices in February of 2022.

112. Additionally, Defendants are equitably estopped from asserting any limitations defense by virtue of their fraudulent concealment and other misconduct as described herein.

113. Further, the limitations period ought to be tolled under principles of equitable tolling.

THE DEFECTIVE OPTETRAK KNEE REPLACEMENT SYSTEM

114. Defendants manufactured and sold the Optetrak Knee Replacement System with the defective tibial trays. The tibia tray was marketed as a component that anchors to the patient's tibia and connects to the artificial knee.

EXATECH VIOLATIONS

115. Upon information and belief, Defendants received numerous reports of adverse events relating to injuries caused by the defective tibial tray but failed to report these events in violation of FDA's requirements in reporting adverse events. 21 U.S.C. § 352(t).

116. Upon information and belief, Defendants engaged in a "silent recall" wherein it replaced the defective tibial trays with a different designed tray. Concurrent with this strategy, Defendants also engaged in a campaign of misinformation wherein any incidents of early failures were blamed on surgeons or patients rather than the defective tibial tray.

117. Based on information and belief, Defendants' Optetrak Knee Replacement Systems with their defective inserts and/or defective tibial trays are considered adulterated pursuant to 21 U.S.C. § 351 because, among other things, they failed to meet established performance standards, and/or methods, facilities, or controls used for their manufacture, packaging, storage, or installation, and are not in conformity with federal requirements in accordance with Current Good Manufacturing Practices ("cGMP") for medical devices. *See* 21 U.S.C. § 351; 21 C.F.R. § 820, *et seq.*

118. Based on information and belief, Defendants' Optetrak Knee Replacement Systems with a defective insert and/or defective tibial tray are considered misbranded because, among

other things, they are dangerous to health when used in the manner prescribed, recommended, or suggested in the labeling thereof. See 21 U.S.C. § 352.

119. Had Defendants complied with the federal requirements regarding cGMP, Defendants' knee implant devices would have been manufactured properly and would not have resulted in injuries to Plaintiff.

EQUITABLE ESTOPPEL AND CONTRA NON VALENTEM

120. Plaintiff incorporates by reference the allegations of the preceding paragraphs of the Complaint as if fully set forth at length herein.

121. Plaintiff invokes the doctrine of contra non valentem as she could not discover the defects and unreasonably dangerous condition of Defendants' defective components.

122. Defendants are estopped from relying on any prescription limitations by virtue of their acts of fraudulent concealment, affirmative misrepresentations, and omissions, which include Defendants' intentional concealment from Plaintiff, Plaintiff's health care professionals and the public that the Optetrak Knee Implant System was unreasonably dangerous and carried serious risks causing injuries.

123. Defendants breached their duty to disclose that the Optetrak Knee Implant System was unreasonably dangerous and carried with it the serious risk of early failure, injury and revision surgery.

124. Defendants breached their duty to notify, inform, or disclose to Plaintiff, Plaintiff's health care professionals or the general consuming public that Defendants' Optetrak Knee Implant System was causing high incidences of injuries and that its use carried with it the serious risk of developing the injuries Plaintiff has suffered and complained of herein.

CAUSES OF ACTION

COUNT I – STRICT LIABILITY – UNREASONABLY DANGEROUS IN COMPOSITION

125. Plaintiffs incorporate by reference each and every paragraph of this Second

Amended Master Complaint as if fully set forth herein and further alleges as follows.

126. The Optetrak Knee Implant System containing the defective insert and/or defective tibial tray was unreasonably dangerous as manufactured, packaged, distributed, marketed and/or sold by the Defendants, as it deviated in a material way from Defendants' own specifications or performance standards for the product and from otherwise identical products manufactured by Defendants, and as defined in the Louisiana Products Liability Act ("LPLA"), Louisiana Revised Statute 9:2800.55.

127. The defective components in the Optetrak Knee Replacement System were a substantial factor in causing Plaintiff's injuries.

128. Defendants are strictly liable for the defective condition of the Optetrak Knee Replacement System; the distribution, marketing, and/or sale of the defective insert and/or the defective tibial tray; and the injuries sustained by Plaintiff.

COUNT II – STRICT LIABILITY – UNREASONABLY DANGEROUS IN DESIGN

129. Plaintiffs incorporate by reference each and every paragraph of this Second Amended Master Complaint as if fully set forth herein and further alleges as follows.

130. Defendants had a duty to design and package the defective insert in a manner that did not present an unreasonable risk of harm or injury to users and patients exposed to their danger, including Plaintiff.

131. The designs of the defective tibial tray and the packaging of the defective insert were unreasonably dangerous for its expected, intended, and/or foreseeable uses, functions, and purposes, as defined in the Louisiana Products Liability Act, Louisiana Revised Statute 9:200.56.

132. The defective tibial tray was not reasonably safe as designed, distributed, marketed, delivered and/or sold by Defendants.

133. The design defects in the defective tibial tray and defective insert and its packaging existed when the device left the Defendants' control.

134. Plaintiff's physicians implanted the defective tibial tray and defective insert in the way they were intended and recommended to be used, making such use reasonably foreseeable to Defendants.

135. The defective tibial trays and the defective inserts and packaging were defective in design and unreasonably dangerous when it entered the stream of commerce and received by Plaintiff, and the foreseeable risks exceeded or outweighed the purported benefits associated with the device.

136. Feasible, safer, alternative designs and packaging providing the same functional purpose were available to the Defendants at the time the defective tibial tray and the defective insert were designed, packaged, and offered for sale in the market.

COUNT III – STRICT LIABILITY-UNREASONABLY DANGEROUS BECAUSE OF INADEQUATE WARNING

137. Plaintiffs incorporate by reference each and every paragraph of this Second Amended Master Complaint as if fully set forth herein and further alleges as follows.

138. Defendants failed to provide adequate warnings with reasonable care regarding dangers in the use and handling of the defective tibial tray and defective insert, as defined in the Louisiana Products Liability Act, Louisiana Revised Statute 9:2800.57.

139. Defendants had a duty to distribute, market, and/or sell the Optetrak Knee Replacement System with adequate warnings that did not present an unreasonable risk of harm or injury to users and patients exposed to their danger, including Plaintiff.

140. The warnings that accompanied the Optetrak Knee Replacement System, with the defective tibial tray and/or defective insert, and its packaging were inadequate, thereby making the

product not reasonably safe for its expected, intended, and/or foreseeable uses, functions, and purposes.

141. In particular, Defendants failed to adequately disclose the danger of the defective tibial tray, particularly when used with a size three femur in combination with a size three tray, as in Plaintiff's implant surgery, given its propensity to undergo substantial early failure due to component loosening, tissue damage, bone loss, osteolysis, other complications, as well as the need for revision surgery.

142. Defendants knew of the defective insert's increased risk of harm to the Plaintiffs and other consumers and that warnings would have been feasible and effective in preventing plaintiff's injuries.

COUNT IV – UNREASONABLY DANGEROUS BECAUSE OF NON-CONFORMITY TO EXPRESS WARRANTY

143. Plaintiffs incorporate by reference each and every paragraph of this Second Amended Master Complaint as if fully set forth herein and further alleges as follows.

144. At the time Defendants applied for the 510(k) premarket approval of its Optetrak Knee Replacement System with the defective insert, Defendants warranted that all components would be supplied, properly packaged according to specifications, and Defendants would conduct package validation testing. Defendants failed to perform the package testing over the course of sales from 2004 through 2022.

145. Defendants warranted that they would comply with 21 CFR Part 820 of the FDA regulations for Current Good Manufacturing Practice (cGMP) requirements to ensure safety and effectiveness of its medical devices, including packaging of finished devices under subpart K and L (subsection 130, 140, 150 of part 820). Defendants violated this warranty.

146. Defendants, in their marketing and advertising, warranted less polyethylene wear

from the Optetrak as compared to other manufacturers' devices. Defendants breached this warranty.

147. These express warranties became part of the basis of the bargain Defendants made with Plaintiffs.

148. Plaintiffs and their healthcare providers relied on Defendants' express warranties in electing to purchase and use their Exactech Devices.

149. By reason of the foregoing, Plaintiffs seek actual damages, costs, and any other just and proper relief available thereunder for the Exactech Devices' breach of express warranty.

COUNT V – REDHIBITION UNDER LA. C.C. ART 2520

150. Plaintiffs incorporate by reference each and every paragraph of this Second Amended Master Complaint as if fully set forth herein and further alleges as follows.

151. The Exactech Devices contain a vice or defect which renders it useless or its use so inconvenient that buyers would not have purchased it.

152. Exactech sold and promoted their total knee replacement devices, which Exactech placed into the stream of commerce. Under Louisiana law, the seller warrants the buyer against redhibitory defects, or vices, in the thing sold. La. C.C. art. 2520. The Exactech Devices, sold and promoted by Exactech, possess a redhibitory defect because they were not manufactured and marketed in accordance with industry standards and/or are unreasonably dangerous, as described above, which renders the subject product useless or so inconvenient that it must be presumed that a buyer would not have bought the subject product had he known of the defect. Pursuant to La. C.C. art. 2520, Plaintiffs are entitled to obtain a rescission of the sale of the Exactech Devices.

153. The Exactech Devices alternatively possesses a redhibitory defect because the Exactech Devices were not manufactured and marketed in accordance with industry standards

and/or are unreasonably dangerous, as described above, which diminishes the value of the Exactech Devices so that it must be presumed that a buyer would still have bought it but for a lesser price. In this instance, Plaintiffs are entitled to a reduction of the purchase price of the Exactech Devices.

154. Exactech is liable as a bad faith seller for selling a defective product with knowledge of the defect, and thus, are liable to Plaintiff for the price of the Exactech Devices with interest from the purchase date, as well as reasonable expenses occasioned by the sale of the Exactech Devices, and attorneys' fees. As the manufacturer of the Exactech Devices, under Louisiana law, Exactech is deemed to know that the Exactech Devices possessed a redhibitory defect. La. C.C. art. 2545.

155. As a result of the Exactech Devices' redhibitory defects, Plaintiffs have suffered actual damages in that each Exactech Device they purchased is worth less than the price they paid and which they would not have purchased at all had they had known of the attendant health risks associated with the use of each Exactech Device.

156. Defendants were both manufacturer and seller of the Optetrak Knee Replacement System and warranted against redhibitory defects regarding defective components when used. Because Defendants were in bad faith and failed to reveal the defects, Defendants are liable for reimbursement of the expenses, damage, and attorneys' fees under Louisiana Civil Code Article 2345.

157. By reason of the foregoing, Plaintiffs seek actual damages, attorneys' fees, costs, and any other just and proper relief available thereunder for the Exactech Devices' redhibitory defects.

COUNT VI - LOSS OF CONSORTIUM AND SERVICES

158. Plaintiffs hereby incorporate by reference all previous paragraphs of this Complaint as if fully set forth herein and further allege as follows.

159. At all relevant times, Plaintiff SANDRA HOYT was and is the lawfully wedded wife of Plaintiff RONALD HOYT, and as such, was and is entitled to the services, consortium, and society of RONALD HOYT.

160. As a result of the foregoing strict products liability, negligence, and breach of warranties by the Defendants, Plaintiff SANDRA HOYT was deprived of the services, consortium, and society of RONALD HOYT.

161. As a direct, proximate, and legal consequence of Defendants' wrongful conduct as described herein, whether through strict liability or negligence, Plaintiff SANDRA HOYT has suffered and will continue to suffer the loss of support, companionship, service, love, affection, society, intimate relations, and other elements of consortium all to the detriment of their marital relationship for which Plaintiff SANDRA HOYT is entitled to compensatory damages in an amount to be proven at trial.

DAMAGES

162. By reason of the foregoing acts, omissions and conduct committed by Defendants, Plaintiffs sustained serious personal injuries, severe pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses, and will sustain future damages, including but not limited to cost of medical care; rehabilitation; home health care; loss of earning capacity; mental and emotional distress and pain and suffering. Accordingly, Plaintiffs are seeking compensatory and special damages, including attorneys' fees and costs, and all other available remedies under the law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, and severally, as follows:

a. Judgment in favor of Plaintiffs and against all Defendants, for damages in such amounts as may be proven at trial;

b. Compensation for both economic and non-economic losses, including but not limited to medical expenses, loss of earnings, disfigurement, pain and suffering, mental anguish, and emotional distress, in such amounts as may be proven at trial;

c. Attorneys' fees and costs;

d. Interest; and

e. Any and all further relief, both legal and equitable, that the Court may deem just and proper.

WHEREFORE, the Plaintiffs demand judgment of and from Defendants in an amount for compensatory damages against all Defendants for pain and suffering actual damages; consequential damages; exemplary damages, jointly and severally against all Defendants; interest on damages (pre- and post-judgment) in accordance with the law; Plaintiffs' reasonable attorney's fees, as well as costs of court and all other costs incurred; and such other and further relief as the Court may deem just and proper.

Dated: August 19, 2022

Respectfully submitted,

By: /s/ Dawn M. Barrios

BARRIOS, KINGSDORF & CASTEIX, LLP
Dawn M. Barrios, Esq. (La. Bar No. 2821)
Zachary L. Wool, Esq. (La. Bar No. 32778)
701 Poydras Street, Suite 3650
New Orleans, LA 70139
Telephone: (504) 524-3300
Facsimile: (504) 524-3313
barrios@bkc-law.com
zwool@bkc-law.com

ROBINS KAPLAN LLP
Rayna E. Kessler, Esq.*
1325 Avenue of the Americas, Suite 2601
New York, New York 10022
Telephone: (212) 980-7431
Facsimile: (212) 980-7499
E-mail: RKessler@RobinsKaplan.com
**Pro Hac Vice* motion to be filed

Attorney for Plaintiffs Ronald Hoyt and Sandra Hoyt

DEMAND FOR JURY TRIAL

Plaintiffs respectfully demand trial by jury of all claims that are so triable.

Dated: August 19, 2022

Respectfully submitted,

By: /s/ Dawn M. Barrios

BARRIOS, KINGSDORF & CASTEIX, LLP
Dawn M. Barrios, Esq. (La. Bar No. 2821)
Zachary L. Wool, Esq. (La. Bar No. 32778)
701 Poydras Street, Suite 3650
New Orleans, LA 70139
Telephone: (504) 524-3300
Facsimile: (504) 524-3313
barrios@bkc-law.com
zwool@bkc-law.com

ROBINS KAPLAN LLP
Rayna E. Kessler, Esq.*
1325 Avenue of the Americas, Suite 2601
New York, New York 10022
Telephone: (212) 980-7431
Facsimile: (212) 980-7499
E-mail: RKessler@RobinsKaplan.com
**Pro Hac Vice* motion to be filed

Attorney for Plaintiffs Ronald Hoyt and Sandra Hoyt